19-**236236**4521-shDocD6752250Filed 19926002011/1261ter1edt 1992600201010251922732:11/2ain 1990clean ent Declaration and 199361161653972art 1 Pg 1 of 68

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Counsel to the Official Committee of Unsecured Creditors of Purdue Pharma L.P., et al.

UNITED STATES BANKRUPTCY COURT SOUTHERN DISTRICT OF NEW YORK

)
In re:) Chapter 11
)
PURDUE PHARMA L.P., et al., 1) Case No. 19-23649 (RDD)
)
Debtors.	(Jointly Administered)
)

DECLARATION OF MITCHELL HURLEY <u>DATED SEPTEMBER 29, 2020</u>

¹ The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield Bio Ventures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

Under 28 U.S.C. § 1746, I, Mitchell Hurley, declare under the penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

- 1. This declaration ("<u>Declaration</u>") is submitted in support of the Official Committee of Unsecured Creditors (the "UCC") of Purdue Pharma, L.P. et al.'s two motions filed contemporaneously with this Declaration entitled (1) Official Committee of Unsecured Creditors' Motion to Compel Production of Purportedly Privileged Documents, or for In Camera Review, Based on Good Cause, Crime Fraud, and At Issue Exceptions to Privilege (the "<u>Exceptions Motion</u>"); and (2) Official Committee of Unsecured Creditors' Motion to Compel Production of Purportedly Privileged Documents, or for In Camera Review, Based on Failure of the Sacklers and the Debtors to Demonstrate Documents Identified on Logs Are Privileged (the "<u>General Challenges Motion</u>," and, together with the Exceptions Motion, the "<u>Motions</u>").²
- 2. I am an attorney in good standing admitted to practice in the State of New York, and I am a partner at the law firm of Akin Gump Strauss Hauer & Feld LLP ("Akin Gump"). I make this Declaration based on my own personal knowledge and belief, and upon documents and information available to me as counsel to the UCC.
- 3. The UCC has met and conferred with counsel for the Sacklers and the Debtors (collectively, the "Withholding Parties") in a good faith effort to resolve by agreement the issues raised by the Motions without the intervention of the Court. The UCC has conferred and corresponded with the Sacklers' and the Debtors' counsel on numerous occasions in an attempt to resolve the UCC's concerns regarding the propriety of the documents withheld or redacted as indicated on the Privilege Logs, as well as the issues regarding the Good Cause, Crime Fraud, and At Issue exceptions to privilege. A selection of the written correspondence most relevant to the

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² Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Motions.

informally resolved some of the UCC's challenges, they could not resolve the issues set forth in the Motions. The UCC, therefore, has filed the Motions in accordance with the briefing schedule provided in the *Amended Stipulation and Agreed Order Regarding Discovery Deadlines and Briefing Scheduling in the Chapter 11 Cases* executed by the Debtors, the Sacklers, the NCSG, the AHC, and the UCC, which was filed and so ordered by the Court on September 28, 2020 [ECF No. 1734].

- 4. Further, the UCC is filing the correspondence with the Withholding Parties in redacted form in an abundance of caution in order to accommodate certain Withholding Parties' prior positions concerning the confidentiality of email address and other information that may be contained therein. By filing in this way, the UCC does not intend to suggest that it agrees the information is or ought to be confidential.
- 5. In addition to the correspondence between the UCC and the Withholding Parties, this Declaration describes the documents and testimony attached to this Declaration that support the UCC's position in both Motions.
- 6. Certain exhibits attached hereto have been designated as Confidential, Highly Confidential, or Professional's Eyes Only by one or more parties to this proceeding and are filed under seal pursuant to the *Second Amended Protective Order* entered in these proceedings [ECF No. 1540].
- 7. Attached hereto as **Exhibit A** is a true and correct copy of an excel workbook containing the entries on Side A's privilege log that the UCC is challenging in the General Challenges Motion and the Exceptions Motion, separated by category based on the tabbed worksheets in the excel workbook. For the Exceptions Motion, the privilege entries are a non-

exhaustive, illustrative list of the Challenged Documents that the UCC believes may fit within the categories of privileged documents of which, by the Exceptions Motion, the UCC is seeking to compel production.

- 8. Attached hereto as **Exhibit B** is a true and correct copy of an excel workbook containing the entries on Side B's privilege log that the UCC is challenging in the General Challenges Motion and the Exceptions Motion, separated by category based on the tabbed worksheets in the excel workbook. For the Exceptions Motion, the privilege entries are a non-exhaustive, illustrative list of the Challenged Documents that the UCC believes may fit within the categories of privileged documents of which, by the Exceptions Motion, the UCC is seeking to compel production.
- 9. Attached hereto as **Exhibit C** is a true and correct copy of an excel workbook containing the entries on Debtors' privilege log that the UCC is challenging in the General Challenges Motion and the Exceptions Motion, separated by category based on the tabbed worksheets in the excel workbook. For the Exceptions Motion, the privilege entries are a non-exhaustive, illustrative list of the Challenged Documents that the UCC believes may fit within the categories of privileged documents of which, by the Exceptions Motion, the UCC is seeking to compel production.
- 10. Attached hereto as **Exhibit 1** is a true and correct copy of an email from J. McClammy to K. Porter, dated May 22, 2020.
- 11. Attached hereto as **Exhibit 2** is a true and correct copy of a letter from M. Hurley to J. Ball, A. Lees, and G. Joseph, dated July 25, 2020.
- 12. Attached hereto as **Exhibit 3** is a true and correct copy of a letter from A. Lees to M. Hurley, dated July 28, 2020.

- 13. Attached hereto as **Exhibit 4** is a true and correct copy of a letter from A. Lees to M. Hurley, dated July 31, 2020.
- 14. Attached hereto as **Exhibit 5** is a true and correct copy of a letter from M. Hurley to J. Ball, A. Lees, and G. Joseph, dated August 5, 2020.
- 15. Attached hereto as **Exhibit 6** is a true and correct copy of a letter from A. Lees to M. Hurley, dated August 7, 2020.
- 16. Attached hereto as **Exhibit 7** is a true and correct copy of a letter from J. Ball to Akin Gump counsel, dated August 10, 2020.
- 17. Attached hereto as **Exhibit 8** is a true and correct copy of a letter from M. Hurley to J. Ball and A. Lees, dated August 12, 2020.
- 18. Attached hereto as **Exhibit 9** is a true and correct copy of a letter from J. Ball to M. Hurley, dated August 16, 2020.
- 19. Attached hereto as **Exhibit 10** is a true and correct copy of a letter from A. Lees to M. Hurley, dated August 16, 2020.
- 20. Attached hereto as **Exhibit 11** is a true and correct copy of a letter from J. Ball, A. Lees, J. Dougherty, and M. Hirschfield to M. Hurley, dated August 17, 2020.
- 21. Attached hereto as **Exhibit 12** is a true and correct copy of a letter from M. Hurley to J. Ball, dated August 18, 2020.
- 22. Attached hereto as **Exhibit 13** is a true and correct copy of a letter from M. Hurley to A. Lees, dated August 20, 2020.
- 23. Attached hereto as **Exhibit 14** is a true and correct copy of a letter from A. Lees to M. Hurley, dated August 22, 2020.

- 24. Attached hereto as **Exhibit 15** is a true and correct copy of a letter from J. Ball to M. Hurley, dated August 23, 2020.
- 25. Attached hereto as **Exhibit 16** is a true and correct copy of a second letter from J. Ball to M. Hurley, dated August 23, 2020.
- 26. Attached hereto as **Exhibit 17** is a true and correct copy of a letter from M. Hurley to B. Kaminetzky, C. Duggan, J. McClammy, M. Clarens, dated August 30, 2020.
- 27. Attached hereto as **Exhibit 18** is a true and correct copy of a letter from M. Hurley to J. Ball, dated August 30, 2020.
- 28. Attached hereto as **Exhibit 19** is a true and correct copy of a letter from M. Hurley to A. Lees, dated August 30, 2020.
- 29. Attached hereto as **Exhibit 20** is a true and correct copy of a letter from A. Lees to M. Hurley, dated September 2, 2020.
- 30. Attached hereto as **Exhibit 21** is a true and correct copy of a letter from J. McClammy to M. Hurley, dated September 8, 2020.
- 31. Attached hereto as **Exhibit 22** is a true and correct copy of a letter from J. Ball to M. Hurley, dated September 8, 2020.
- 32. Attached hereto as **Exhibit 23** is a true and correct copy of a letter from M. Hurley to A. Lees, dated September 12, 2020.
- 33. Attached hereto as **Exhibit 24** is a true and correct copy of a letter from M. Hurley to J. Ball, dated September 12, 2020.
- 34. Attached hereto as **Exhibit 25** is a true and correct copy of a letter from M. Hurley to J. McClammy, dated September 13, 2020.

- 35. Attached hereto as **Exhibit 26** is a true and correct copy of a letter from J. Ball to Akin Gump counsel, dated September 17, 2020.
- 36. Attached hereto as **Exhibit 27** is a true and correct copy of a letter from A. Lees to M. Hurley, dated September 17, 2020.
- 37. Attached hereto as **Exhibit 28** is a true and correct copy of a letter from M. Hurley to A. Lees, dated September 19, 2020.
- 38. Attached hereto as **Exhibit 29** is a true and correct copy of a letter from M. Hurley to J. McClammy, dated September 21, 2020.
- 39. Attached hereto as **Exhibit 30** is a true and correct copy of a letter from M. Hurley to A. Lees, dated September 22, 2020.
- 40. Attached hereto as **Exhibit 31** is a true and correct copy of a letter from J. Ball to Akin Gump counsel, dated September 22, 2020.
- 41. Attached hereto as **Exhibit 32** is a true and correct copy of a letter from M. Hurley and A. Troop to J. McClammy and P. Fitzgerald, dated September 23, 2020.
- 42. Attached hereto as **Exhibit 33** is a true and correct copy of a letter from M. Hurley to J. McClammy, dated September 24, 2020.
- 43. Attached hereto as **Exhibit 34** is a true and correct copy of a letter from A. Lees to M. Hurley, dated September 24, 2020.
- 44. Attached hereto as **Exhibit 35** is a true and correct copy of a letter from M. Hurley to J. Ball, dated September 24, 2020.
- 45. Attached hereto as **Exhibit 36** is a true and correct copy of a letter from M. Hurley to A. Lees, dated September 25, 2020.

- 46. Attached hereto as **Exhibit 37** is a true and correct copy of a letter from M. Grier to M. Huebner, M. Hurley, R. Ringer, and A. Troop, dated September 26, 2020.
- 47. Attached hereto as **Exhibit 38** is a true and correct copy of a letter from A. Lees to M. Hurley, dated September 28, 2020.
- 48. Attached hereto as **Exhibit 39** is a true and correct copy of an email from J. McClammy to G. Feiner, dated May 11, 2020.
- 49. Attached hereto as **Exhibit 40** is a true and correct copy of a letter from J. McLaughlin to K. Porter, dated April 9, 2020.
- 50. Attached hereto as **Exhibit 41** is a true and correct copy of a letter from M. Hirschfield to A. Vinson Crawford, dated September 16, 2020.
- 51. Attached hereto as **Exhibit 42** is a true and correct copy of a letter from M. Leventhal to J. McClammy, C. Duggan, and C. Oluwole, dated September 26, 2020.
- 52. Attached hereto as **Exhibit 43** is a true and correct copy of an excerpt from the transcript of the deposition of David Sackler: 66:13-18; 86:20-87:10; 156:5-157:21; 190:6-15; 211:9-224:1; 225:6-232:17; 379:6-380:3; dated August 28, 2020.
- 53. Attached hereto as **Exhibit 44** is a true and correct copy of an excerpt from the transcript of the deposition of Marianna Sackler: 4:19-22; 302:14-25; dated September 2, 2020.
- 54. Attached hereto as **Exhibit 45** is a true and correct copy of an excerpt from the transcript of the deposition of Stephen Ives: 5:4-6; 31:23-37:21; 309:19-310:14; dated September 22, 2020.
- 55. Attached hereto as **Exhibit 46** is a true and correct copy of excerpts from the transcript of the deposition of Ilene Sackler Lefcourt: 78:7-12; 91:18-92:7; dated September 18, 2020.

- 56. Attached hereto as **Exhibit 47** is a true and correct copy of an excerpt from the transcript of the deposition of Dame Theresa Sackler: 50:18-52:6; 63:25-65:16; 452:21-453:12; dated September 23-24, 2020.
- 57. Attached hereto as **Exhibit 48** is a true and correct copy of a Memorandum of Understanding Regarding Joint Defense and Common Interest dated May 15, 2018, as sent by E. Lilburn to M. Hurley on July 31, 2020.
- 58. Attached hereto as **Exhibit 49** is a true and correct copy of an email dated March 31, 2015 with an attached document entitled "Report of SDB Activities and Responsibilities," which was produced to the UCC under the Bates numbers PPLPUCC000336422 and PPLPUCC000336423, respectively.
- 59. Attached hereto as **Exhibit 50** is a true and correct copy of a document entitled "Purdue Pharma Inc. Board of Directors," which was produced to the UCC under the Bates number PPLPUCC500140094.
- 60. Attached hereto as **Exhibit 51** is a true and correct copy of Mortimer-Side Informational Presentation, Nov. 22, 2019.
- 61. Attached hereto as **Exhibit 52** is a true and correct copy of an email chain dated August 28, 2013 among Jonathan Sackler and Dame Theresa Sackler, which was produced to the UCC under the Bates number MDSF00019408.
- 62. Attached hereto as **Exhibit 53** is a true and correct copy of an email dated May 3, 2010, which was produced to the UCC under the Bates number MSF00077969.
- 63. Attached hereto as **Exhibit 54** is a true and correct copy of a "Family Council Meeting" agenda for a meeting dated November 5, 2012, which was produced to the UCC under the Bates number PPLPUCC000620611.

- 64. Attached hereto as **Exhibit 55** is a true and correct copy of an email chain dated September 22, 2017, which was produced to the UCC under the Bates number MSF00591611.
- 65. Attached hereto as **Exhibit 56** is a true and correct copy of an email chain among Jonathan White and Dame Theresa Sackler from June 19, 2015, which was produced to the UCC under the Bates number MSF90010331.
- 66. Attached hereto as **Exhibit 57** is a true and correct copy of an email chain dated June 12, 2015, which was produced to the UCC by Beth Cohen under the Bates numbers BCOH0000049.
- 67. Attached hereto as **Exhibit 58** is a true and correct copy of excerpts from a December 6, 2019 presentation by Joseph Hage Aaronson LLC, on behalf of the Raymond-side Sacklers entitled "*In Re: Purdue Pharma L.P.*, *et al.*: Presentation of Defenses: Pursuant to November 5, 2019 Amended Stipulation ¶ 17(b) (ECF No. 431)."
- 68. Attached hereto as **Exhibit 59** is a true and correct copy of an email chain dated March 3, 2010, which was produced to the UCC under the Bates numbers PPLPC012000259875.
- 69. Attached hereto as **Exhibit 60** is a true and correct copy of a native file containing a presentation entitled "Purdue Pharma L.P. and Independent Associated Companies: Insurance Update" dated September 2012, which was produced to the UCC under the Bates number PWG004469106.
- 70. Attached hereto as **Exhibit 61** is a true and correct copy of an email chain dated April 13, 2012 attaching a presentation produced in native format entitled "OxyContin Market Events: 4/12/12 <u>FINAL</u>," which was produced to the UCC under the Bates numbers PPLPC012000372436.

- 71. Attached hereto as **Exhibit 62** is a true and correct copy of an email chain dated November 20, 2006, which was produced to the UCC under the Bates numbers PPLPC057000003694.
- 72. Attached hereto as **Exhibit 63** is a true and correct copy of an email chain dated May 15, 2007, which was produced to the UCC under the Bates numbers PWG004474511.
- 73. Attached hereto as **Exhibit 64** is a true and correct copy of an email chain dated May 17, 2007, which was produced to the UCC under the Bates numbers PPLPUCC002683256.
- 74. Attached hereto as **Exhibit 65** is a true and correct copy of an email chain dated February 27, 2007, which was produced to the UCC under the Bates numbers PPLPUCC000555709.
- 75. Attached hereto as **Exhibit 66** is a true and correct copy of an email chain dated June 25, 2007, which was produced to the UCC under the Bates number PPLPUCC000886987.
- 76. Attached hereto as **Exhibit 67** is a true and correct copy of an email chain dated February 13, 2008, which was produced to the UCC under the Bates numbers PPLPUCC000177443.
- 77. Attached hereto as **Exhibit 68** is a true and correct copy of an email chain dated June 22, 2007, which was produced to the UCC under the Bates numbers PWG004473999.
- 78. Attached hereto as **Exhibit 69** is a true and correct copy of an email chain dated July 26, 2007 attaching a document entitled "Confidential Memorandum to Jon Sackler," which was produced to the UCC under the Bates numbers PPLPUCC9000491386.
- 79. Attached hereto as **Exhibit 70** is a true and correct copy of a document entitled "Memorandum to Dr. Richard Sackler. From: F. Peter Boer" dated April 12, 2008, which was produced to the UCC under the Bates numbers PDD9316314303.

- 80. Attached hereto as **Exhibit 71** is a true and correct copy of an email chain dated February 22, 2008, which was produced to the UCC the Debtors under the Bates numbers PPLPC042000011911.
- 81. Attached hereto as **Exhibit 72** is a true and correct copy of excerpts from a December 6, 2019 presentation by Debevoise & Plimpton, on behalf of the Mortimer-side Sacklers entitled "Presentation of Defenses ('Side A'): Pursuant to November 5, 2019 Amended Stipulation ¶ 17(b) (ECF No. 431)."
- 82. Attached hereto as **Exhibit 73** is a true and correct copy of a WhatsApp conversation from October 2017, which was produced to the UCC under the Bates number MSF00023231.
- 83. Attached hereto as **Exhibit 74** is a true and correct copy of a WhatsApp conversation from 2017 to 2019, which was produced to the UCC under the Bates number MSF00022423.
- 84. Attached hereto as **Exhibit 75** is a true and correct copy of an email chain dated December 21, 2011, which was produced to the Senate Finance Committee by Purdue prior to Purdue's bankruptcy filings under the Bates number SFC00007403.
- 85. Attached hereto as **Exhibit 76** is a true and correct copy of an email chain dated March 6, 2015, which was produced to the UCC under the Bates number PNY000485015.
- 86. Attached hereto as **Exhibit 77** is a true and correct copy of an email chain dated October 20, 2017, which was produced to the UCC under the Bates number MDSF00019747.
- 87. Attached hereto as **Exhibit 78** is a true and correct copy of a document entitled "Purdue Quarterly Report to the Board April 15, 2008," which was produced to the UCC under the Bates numbers PWG004497873.

- 88. Attached hereto as **Exhibit 79** is a true and correct copy of an email chain dated December 8, 2011, which was produced to the UCC under the Bates numbers PWG004463776.
- 89. Attached hereto as **Exhibit 80** is a true and correct copy of a presentation entitled "Risk Identification and Mitigation: Selected Risks," dated September 30, 2013, which was produced to the UCC by the Debtors under the Bates numbers PPLPC031001489270.
- 90. Attached hereto as **Exhibit 81** is a true and correct copy of a presentation entitled "Risk Identification and Mitigation: Selected Risks," dated December 1, 2014, which was produced in native format to the UCC by the Debtors under the Bates number PPLPC032000394439.
- 91. Attached hereto as **Exhibit 82** is a true and correct copy of a Purdue Board Meeting Agenda and materials, dated September 13, 2018.
- 92. Attached hereto as **Exhibit 83** is a true and correct copy of an email dated May 15, 2012 attaching a letter from the United States Senate Committee on Finance to John H. Stewart, dated May 8, 2012, which was produced to the UCC under the Bates numbers RSF00679318.
- 93. Attached hereto as **Exhibit 84** is a true and correct copy of a presentation entitled "4Q12 Compliance Report to the Board of Directors," dated January 2013, which was produced in native format to the UCC under the Bates number PPLPUCC001456442.
- 94. Attached hereto as **Exhibit 85** is a true and correct copy of an excerpt of a Board presentation dated May 15, 2014, which was produced to the UCC under the Bates numbers PPLP004411166.
- 95. Attached hereto as **Exhibit 86** is a true and correct copy of an excerpt of a Board presentation dated April 21, 2015, which was produced to the UCC under the Bates numbers PPLP004412071.

- 96. Attached hereto as **Exhibit 87** is a true and correct copy of a Distribution Agreement dated October 24, 1991, which was produced to the UCC under the Bates numbers MSF00026491.
- 97. Attached hereto as **Exhibit 88** is a true and correct copy of excerpts of Board decisions dated January 15, 2013, which was produced to the UCC under the Bates numbers PPLP004417308.
- 98. Attached hereto as **Exhibit 89** is a true and correct copy of an email chain dated July 24, 2015, which was produced to the UCC under the Bates number PPLPUCC9002715623.
- 99. Attached hereto as **Exhibit 90** is a true and correct copy of an email chain dated September 9, 2014, which was produced to the UCC under the Bates numbers MDSF00018083.
- 100. Attached hereto as **Exhibit 91** is a true and correct copy of email correspondence from September 5, 2020 to September 25, 2020 between M. Hirschfield and A. Vinson Crawford, among others.
- 101. Attached hereto as **Exhibit 92** is a true and correct copy of excerpts of Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication in the case *In re National Prescription Opiate Litigation*, Case No. 17-md-2804, United States District Court for the Northern District of Ohio, dated July 19, 2019, Doc. No. 1910-1.
- 102. Attached hereto as **Exhibit 93** is a true and correct copy of excerpts of Plaintiffs' Consolidated Reply Memorandum in Further Support of Plaintiffs' Motions for Partial Summary Adjudication in the case *In re National Prescription Opiate Litigation*, Case No. 17-md-2804, United States District Court for the Northern District of Ohio, dated August 26, 2019, Doc. No. 2545.

- 103. Attached hereto as **Exhibit 94** is a true and correct copy of "An Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances" filed in the case *In re National Prescription Opiate Litigation*, Case No. 17-md-2804, United States District Court for the Northern District of Ohio, dated January 31, 2020, Doc. No. 3124-14.
- 104. Attached hereto as **Exhibit 95** is a true and correct copy of an excerpt of a United States Department of Justice Civil Proof of Claim Form in these cases dated July 30, 2020.
- 105. Attached hereto as **Exhibit 96** is a true and correct copy of an excerpt of a United States Department of Justice Criminal Proof of Claim Form Addendum in these cases dated July 30, 2020.
- 106. Attached hereto as **Exhibit 97** is a true and correct copy of a letter from J. Sorkin to K. Marino, dated July dated September 15, 2020.
- 107. Attached hereto as **Exhibit 98** is a true and correct copy of an email from K. Marino to J. Sorkin, dated September 28, 2020.
- 108. Attached hereto as **Exhibit 99** is a true and correct copy of the April 14, 2009 Decision regarding "Funding Rhodes Pharmaceuticals L.P.," which was produced to the UCC under the Bates number PPLPUCC000619871.
- 109. Attached hereto as **Exhibit 100** is a true and correct copy of April 1, 2010 Decision regarding "Purdue Pharma L.P. 2Q 2010 Distribution," which was produced to the UCC under the Bates number PPLPUCC000440913.
- 110. Attached hereto as **Exhibit 101** is a document describing the categories of privileged documents (namely, the Fiduciary Documents, the Crime Fraud Documents, and the At Issue Documents) that the UCC is seeking to compel as set forth in the Motions.

- 111. Attached hereto as **Exhibit 102** is a document entitled "Dr. Craig Landau Appointed President and CEO Purdue Pharma L.P.," dated August 28, 2018, was produced to the UCC by the Debtors under the Bates number PPLPUCC000013176.
- 112. Attached hereto as **Exhibit 103** is true and correct copy of a letter from Mara Leventhal (Joseph Hage Aaronson) to James I. McClammy (Davis Polk) et al. dated September 26, 2020.
- 113. Attached hereto as **Exhibit 104** is a true and correct copy of the April 16, 2013 Beacon Company SEC Form 4.
- 114. Attached hereto as **Exhibit 105** is a true and correct copy of the April 16, 2013 Rosebay Medical Company L.P. SEC Form 4.
- 115. Attached hereto as **Exhibit 106** is a true and correct copy of the March 4, 2003 Shareholders' Agreement (Purdue Pharma Inc.), which was produced to the UCC under the Bates number MSF00026639.
- 116. Attached hereto as **Exhibit 107** is a true and correct copy of the Minutes of a March 4, 2003 Meeting of the Board of Directors of Purdue Pharma Inc., which was produced to the UCC under the Bates number PPLPUCC500647319.
- 117. Attached hereto as **Exhibit 108** is a true and correct copy of the December 4, 2015 email from Kathe Sackler, which was produced to the UCC under the Bates number MSF00806366.
- 118. Attached hereto as **Exhibit 109** is a true and correct copy of a document entitled "MNP Consulting Limited List of Directors," sent as an attachment to a July 14, 2020 email from J. Upin to A. V. Crawford RE: IAC custodians follow up.

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Executed on: September 29, 2020

/s/ Mitchell Hurley Mitchell Hurley

EXHIBIT 50

UNREDACTED - CONTAINS OUTSIDE PROFESSIONALS ENERGY OF ALL INFORMATION 23:32:12 Hurley TREAT SUBJECT TO PROTECTIVE ORDER LARGE PLANTAGE PROFESSION ALL SUBJECT TO PROTECTIVE ORDER LARGE PURDUE PHARMA INC. BOARD OF DIRECTORS

<u>Name</u>	Class	Date Appointed	Date Resigned
Robert S. Miller	Chairman	July 1, 2018	N/A
Kenneth Buckfire	At Large	May 14, 2019	N/A
Mike Cola	At Large	February 7, 2019; ¹ amended July 25, 2019 to become at large	N/A
John S. Dubel	At Large	July 2, 2019	N/A
Anthony M. Roncalli	Class B	December 1, 2018	N/A
Cecil B. Pickett	Class A	January 21, 2010	N/A
Peter Boer	Class B	April 18, 2008	N/A
Mortimer D.A. Sackler	Class A	January 15, 1993	January 16, 2019
Jonathan D. Sackler	Class B	October 2, 1990	December 8, 2018
llene Sackler Lefcourt	Class A	October 2, 1990	October 9, 2018
Kathe A. Sackler, M.D.	Class A	October 2, 1990	September 27, 2018
Theresa E. Sackler	Class A	January 15, 1993	September 7, 2018
David A. Sackler	Class B	July 19, 2012	August 14, 2018
Richard S. Sackler, M.D.	Class B	October 2, 1990	July 24, 2018
Jacques Theurillat	Class A	February 2, 2016	June 4, 2018

¹ Cola was appointed on February 7, 2019 to Class A. He became a part of the At Large Class on July 25, 2019.

CPAM: 93839291.1

<u>Name</u>	Class	Date Appointed	Date Resigned
Paulo Costa	Class B	April 25, 2012	January 30, 2018
Ralph Snyderman	Class B	August 1, 2012	October 30, 2017
Beverly Sackler	Class B	January 15, 1993	October 17, 2017
Raymond R. Sackler, M.D.	Class B	October 2, 1990	July 17, 2017 ²
Judy Lewent	Class A	March 20, 2009	December 31, 2014
Mortimer D. Sackler, M.D.	Class A	October 2, 1990	March 24, 2010 ²
William Loomis	Class B	May 14, 2008	July 31, 2008
Robert Shapiro	Class A	February 4, 2005	November 21, 2005
Samantha Hunt	Class A	January 15, 1993	March 8, 2003
Jonathan G. White	Class A	June 25, 1998	September 5, 2002

² Date of death.

EXHIBIT 60

Produced Natively

Produced by Purdue Pharma L.P., pursuant to Multistate Work Group Requests Subject to the Confidentiality Agreement dated February 16, 2017 Confidential Treatment Requested

Purdue Pharma L.P. and Independent Associated Companies

Insurance Update

September, 2012



Executive Summary

The following presentation is a summary of insurances held for group companies at a group level. In addition to this coverage, group companies also have local policies that are required to be held locally, e.g. German Pharma Fund (product liability.)

¬ Conclusion:

Group	coverage	e is	□overall	□aded	uate
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- ☐ U.S. product liability insurance is not available in the U.S. for OxyContin® and may not be available for other C-II medicines.
- □ U.S. product liability insurance on other products is expensive, restrictive, and not available at adequate levels so is not recommended.
 - For example, a \$100 million policy, excess of \$50 million retention with OxyContin excluded, could cost \$5 million in annual premium plus significant restrictions and subject to extensive due diligence.
- □ We recommend continuing in place insurance coverage as is.



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Agenda

- □ Product Liability Insurance Available to Purdue US
- ☐ Current IAC Global Insurance Program



Product Liability Insurance Available to Purdue US

(These are preliminary, pre-due diligence indications only.)

Product Liability Insu	urance (all US products including OxyContin®)
Description	□□ Insurance broker: Marsh
	☐☐ Insurance limit: \$100 million (Batch Retention: OxyContin => \$50-100mm; Non-OxyContin => \$25-50mm)
	□□ Co-insurance: likely required co-insurance up to 25%
	□□ Application process involves significant disclosure and input from the business
	□□ Total of three presentation days at London, Bermuda, and New York with key Purdue executives
	□□ Some limitation/exclusion clauses regarding OxyContin are likely
Time to Completion	4 - 5 months
Premium / Cost	\$3.0 ^(a) - 4.5 million p.a.
Commission	Commission is embedded in the premium
	Explicit: \$300,000 or 10% of premium, whichever is lower; (plus \$50,000 retainer upon bindable quotes □credited against premium if program is incepted)
RDUE (a) Very high retention; high co-insura	ance; some limitation/exclusion. Confidential Proprietary Information For

Redacted



Declaration and Exhibits Part 1 Pg 28 of 68

Product Liability Insurance Possible Next Steps

If Purdue pursues the next steps:

- □ Broker (Marsh) will identify insurers with serious interests.
- Purdue executes CDAs with these insurers.
- Due diligence by insurers
 - Application process requiring full disclosure with focus in drug discovery process, research institution fundings, clinical trials, adverse events, contractual process with vendors and customers, marketing/sales process, risk management & loss control, loss and potential loss history.
 - □ Road show presentation in the US, Bermuda, and London/Dublin. Topics to include epidemiology reports on reformulated OxyContin®, REMS program, compliance, supply chain security, attributes of key products (focus on differentiating delivery system and API of BuTrans®, and Intermezzo from current product on the market).
- n This is on a best efforts basis. There are no guarantees.



Insurance Overview

Product Liability:

□ Purdue US

PURDUE

- □\$10 million fronted policy (posted \$10 million Letter Of Credit as collateral), no clinical trials coverage, defense within limits, no risk transfer.
- □ Rhodes Pharmaceuticals has standalone \$10 million risk transfer insurance policy.
- □ RoW (including Canada)
 - □ \$10 million fronted policy (Purdue posted \$2.5 million Letter of Credit as collateral) for product liability and \$20 million fronted policy for clinical trials.
 - □ \$45 million of risk transfer insurance in excess of fronted policy. Excludes claims related to abuse and diversion of OxyContin and OxyNeo.

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Insurance Overview

General Liability, Employer Liability, Auto Liability:

- □ US \$2 million primary policies. \$100 million umbrella/excess policies above primary policies.
- □ Canada/RoW □\$2 million primary global General Liability policy (with local GL policies where required). Primary Auto and Workers Compensation/Employers Liability policies are purchased locally as required by statute. The group has \$2 million difference in conditions policies that fills in any insurance gaps between a local Auto and Employers Liability policies and the 1st layer of the \$100 million umbrella/excess policies above primary policies.



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Insurance Overview

Property:

- - □\$1 billion limits for property and Business Interruption
 - □ \$250 million sublimit for flood
 - □ \$100 million sublimit for earthquake
 - □ \$50 million limit for Contingent Business Interruption
 - ☐ Various other sublimits
- □ RoW □same as above except:
 - □\$100 million sublimit for flood



Insurance Overview

Ocean Cargo:

- □ Within Continental US and Canada \$35 million limits per shipment
- □ RoW (within national borders) \$25 million limits per shipment
- □ Cross border exports \$10 million per shipment



Insurance Overview

Directors & Officers Liability:

- □ Globally \$58 million in limits
- □ Ex US □Additional \$25 million in limits that would not be eroded by US claims.

Employment Practices Liability:

□n \$15 million limits

Fiduciary Liability:

□n \$15 million limits

Crime:

□n \$15 million limits



EXHIBIT 70

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Memorandum to Dr. Richard Sackler

From: F. Peter Boer

April 12, 2008

Re: CEO Considerations

This memo is responsive to your request for an update to our correspondence of Dec 28, 2007 and thereafter regarding the key issues and considerations in selecting a CEO for Purdue USA.

Assumptions

Let me begin by framing the situation as I currently see it.

My central assumption is that Purdue must be managed for long-term success. While it is very possible that the company can be recapitalized using debt, or sold to a strategic buyer, the perception of a sound long-term plan and effective management will translate into maximizing value for the present owners. Conversely, a perception of a hasty exit will unnecessarily diminish their bargaining position.

Secondly, there are two risks the owners cannot effectively control. The first is the availability of a meaningful amount of debt on reasonable terms (rate and covenants). The second is the entrance of strategic buyers both able to finance an acquisition and a conviction that Purdue is among the best investments currently available to them. We and our advisers will have some control over buyers' perception of Purdue, but not over their competing investment opportunities or strategies. These risks again argue for operating the company for sustained value.

In the event that a favorable deal cannot be structured during 2008, the most certain way for the owners to diversify their risk is to distribute more free cash flow to themselves if they cannot purchase diversifying assets. Top management must be aligned to this reality, which intrinsically competes with the use of free cash flow to maximize growth and diversification for Purdue itself. In the end, the right targets will depend on a realistic assessment of the quality of the investment opportunities available to Purdue, which includes the competence of its management team to execute on these opportunities.

Special CEO Considerations — These are for the Board only and not for Management discussions at this time.

Purdue's situation is unique, particularly in its dangerous concentration of risk, and this circumstance of itself makes CEO selection considerations unique.

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Possible investors in, or acquirers of. Purdue will view the top management team differently. Passive investors will include the competence of this team and its long-term commitment to the Company as an element of value. On the other hand, some strategic buyers would contemplate synergies and intend to replace executives in due course with their own people and systems.

The Purdue CEO and his top team are thus in an interesting and conflicted position. Under some circumstances, such as merger with a public company, they may gain exceptional opportunities to increase personal wealth through equity packages. On the other hand, they may at the end of the day gain only the one-time benefits specified in change-of-control or severance agreements. Their perception of this equation will depend on whether they are contemplating retirement, or whether they feel they are well positioned to advance their careers elsewhere in the industry. Inevitably, there will be intense speculation by executives on the probable outcome for the Company.

Character — as we recently discussed in NY over dinner — becomes a paramount consideration under these circumstances. People who will shift their lovalties rapidly under stress and temptation can become a liability from the owners' viewpoint. My opinion is that JHS is very favorably strong in this dimension.

Priority 1. Sustaining, protecting, and possibly extending the cash flow afforded by the Oxycodone franchise

The primary metric and source of value over the medium term is EBITDA through our period of exclusivity, currently estimated to be through 2013. [It must be remembered that we need to start pediatric studies to earn the additional 6 months of patent life early enough to assuredly accomplish approval.] This must be protected through operational excellence and astute positioning versus potential competitors.

There seem to be a few opportunities to extend the franchise to 2015 or beyond. These include OTR patents, low ABUK, intermediate and extended strengths, and antagonist combinations, not to mention new concepts. Even if they are long shots, success with these projects would be extremely valuable.

Major risks must be avoided, especially non-compliance with the Corporate Integrity Agreement, and employee loss of confidence in a period of turbulence.

Priority 2. Building an organization and business systems that will improve efficiency and decision-making, while trimming redundant procedures or staff

The revitalization and reorganization of the Company, including top executive ranks, is a priority. In particular, the absence of a Chief Scientific Officer to coordinate and prioritize R&D programs is a major gap, and the question has been raised whether Business Development should be led by a more seasoned executive if we are to

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accomplish meaningful results in the time frame. Manufacturing appears to be in excellent shape — with the exception of the Totowa inefficiencies and the lack of a viable and cost-effective backup plan — while the role and performance of other key functions such as Sales and Marketing, Finance, Legal and Human Resources need to be carefully assessed. An important issue is whether recruiting a COO would be helpful. Another is whether adequate succession potential is in place in middle level positions across the functions.

The CEO must ensure cooperation, communication, and coordination among departments, and work to eliminate silos and roadblocks to effective action. The repair of systems and procedures, many of which are deficient, is an important task, some of which must be delegated.

The CEO must define the management teams' goals, incentives, and metrics to implement both the annual and strategic plans.

Priority 3. Working with the Board on Company strategy, including financing or recapitalizing the Company

There are several key strategic issues that deserve prompt attention:

- 1) The correct allocation of free cash flow between distributing profits to owners versus to new investment opportunities
- 2) The quality and size of external investment opportunities. Overestimation of these, and our ability to exploit them can lead to misallocation of resources.
- 3) The allocation of internal R&D funds between medium term and long-term opportunities (my definition of medium-term is generating meaningful EBITDA before 2013). While some long-term effort is necessary, the priority is EBITDA impact before 2013.
- 4) The amount of cash on the balance sheet to ensure liquidity and respond to opportunity. This judgment will affect the rate of distribution, especially in the short term.

A flawed strategic plan or failure in execution of a good strategy are important risks.

When a potential transition to a new owner comes into sight, the commitment of senior management to lead this process with enthusiasm to a successful outcome will be critical.

Priority 4. Investing in acquisitions and R&D programs that will create mediumterm value.

A successful CEO will diversify sources of cash flow over the next five years to reduce the company's vulnerability to loss of exclusivity, and increase investor estimates of ongoing EBITDA beyond this timeframe. Some EBITDA can be "bought" through

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shrewd acquisitions and more can be created by successful new product development. Setting an achievable target is a key task.

While abundant cash flow for investment is in principle available, the key judgment is how many opportunities can be realized within the constraints of the external marketplace and integrated and pursued given modest personnel resources, the need for investments to be value-creating, and the resource limitations of a relatively small company. Considerable leverage is available through associated businesses in Europe, Canada, Asia and Rhodes, and some of Purdue's best opportunities may come from creative exploitation of the opportunities these present.

Managing priority 4) is critical because it typically involves complex situations and time-consuming meetings, and the urgent can easily distract from the truly important. The CEO must provide leadership, guidance, and encouragement, but this is not CEO work. Effective senior executives in R&D, Finance and Business Development can help greatly.

Personal Considerations

The CEO's job is challenging. I have noted he must divide his time among four general priorities, and achieve results within the short time frame afforded by our exclusivity position.

- 1) Sustaining, protecting, and possibly extending the cash flow afforded by our Oxycodone franchise.
- 2) Building an organization and business systems that will improve efficiency and decision-making, while trimming redundant procedures or staff.
- 3) Working with the Board on company strategy, including financing or recapitalizing the Company
- 4) Investing in acquisitions and R&D programs that will create medium-term value.

An immediate opportunity is to reduce the time committed to managing Canada by appointing a President/COO for this region, with JHS retaining at least temporarily the CEO position. The division of responsibility between Canadian CEO and COO will involve three elements: formulating Canada strategy (agreement on goals), delegation of authority, and structuring effective reporting relationships. It should be expected that the COO in Canada will join the rank of possible successors to JHS, AW and HG. It will be important to firmly establish the amount of time JHS is expected to commit to the US business. This division of time should also be reflected in the structure of the pay package, i.e. US W-2 versus Canadian T-4.

A second possible opportunity is to recruit a COO for Purdue USA. A positive decision will affect JHS's personal priorities and begin to address the issue of succession

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planning. There appear to be no current internal or external candidates. The wrong incumbent in this sensitive job would be a serious risk. A COO will help with priorities 1) and 2) and will be another possible successor to our current Area Managers.

Finally, there are a group of issues particular to JHS including dual residence, tax, travel to Toronto, vacation entitlements, health insurance, and other fringe benefits. (These details must be considered with a view to the differences between US and Canadian practice by human resource professionals.)

There are several issues with regard to long-term incentives, vesting, and possible change-of-control agreements should a strategic buyer emerge. These incentives must be correctly aligned with the priorities above, and in time with a strategic plan that is supported by the Board. I have recently written a separate memo to Jon Sackler on why I think that plan might be a joint effort by the Board and Management that reflects the owner's needs as well as those of the Company. But again, this is not urgent and can be approached in the coming months as we explore strategic options.

Conclusion

I hope this summary of the key considerations in our decision to go forward will be helpful to the Search Committee, and more importantly to setting the stage for an effective transition and mutual understanding between CEO and Board. I'm sure you will get some other suggestions from Committee members and I look forward to the discussion.

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EXHIBIT 78

Purdue

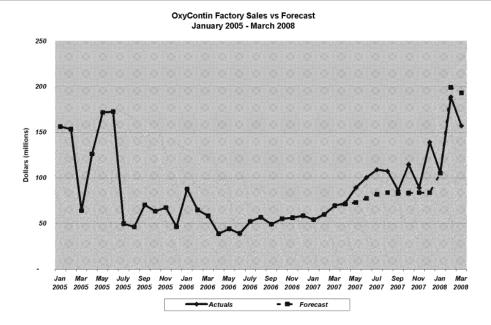
Quarterly Report to the Board

April 15, 2008

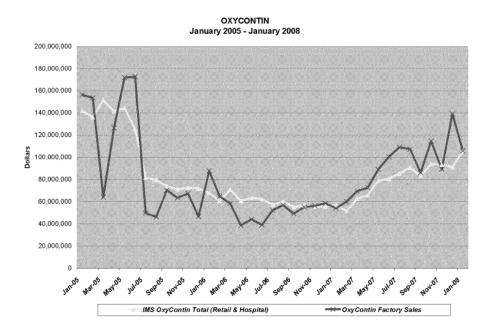
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SALES & MARKETING



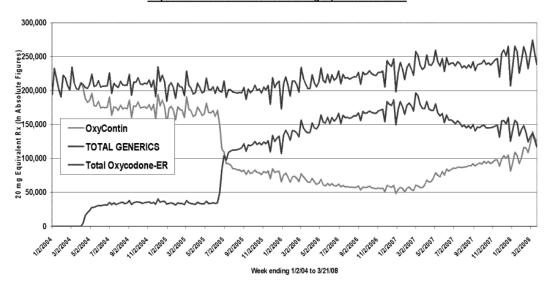
- Graph above depicts actual factory sales vs. forecast.
- YTD Factory Sales through March 2008 were \$451,831,401.
- YTD Factory Sales through March 2008 were 25.36% of forecast.



- Except for November 2007, Factory sales through January were running above demand.
- Also, be aware, some types of business are now captured in the IMS data, such as Outpatient clinics and pharmacies. These sales are included starting with January 2008 data.

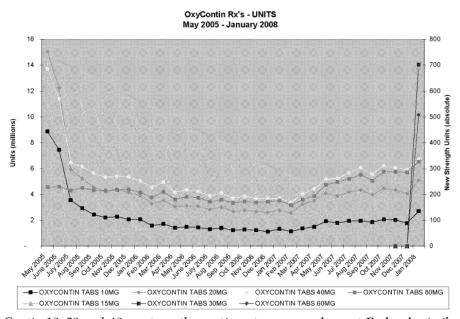
OxyContin Weekly Prescriptions versus Generics

OxyContin versus Generics - On a 20 mg Equivalent Rx Basis



- Total Generics are showing a steady decline as OxyContin is growing.
- Total Oxycodone ER continues to increase as well.

OxyContin Prescription Units (Millions of Tablets)



- OxyContin 10, 20 and 40mg strengths continue to grow and are at Rx levels similar to 1 $\frac{1}{2}$ 2
- OxyContin 80mg continues to grow and is at Rx levels not seen in over 2 years.

SUPPLY CHAIN MANAGEMENT

OxyContin:

Production Facility Primary Metrics –

Wilson domestic narcotic distribution shipped over \$474M in Q1 while maintaining a 99.9% on time and in full customer shipment rating. Total production output for the Wilson facility increased by 300% in Q1 while maintaining 100% in schedule adherence:

- 1. <u>Distribution</u> Distribution shipped 1154 orders and 4433 line items during Q1 which is a 60% increase over last quarter. During Q1, 100% of the OxyContin 100 count bottles were shipped RFID enabled and e222 volume rose to 21% of orders received.
- 2. Export Successfully completed 7 of the 7 export orders received during the quarter.
- 3. <u>Manufacturing</u> 100% schedule adherence by completing 108 of 108 batches scheduled (including 15 'New Formulation' validation batches).
- 4. Packaging 100% schedule adherence by completing 100 of 100 batches scheduled.
- Oxy NF validation and preparation for approval:
 - 1. Wilson validation batches on schedule and data package generation underway.
 - 2. Totowa: manufacture of clinical/stability batches for clinical supplies underway.
- Oxy Intermediate Strengths: launch batches of 15, 30, and 60 mg were shipped in January 2008.
- RFID Gen 2: Systech software upgrades have been completed on both packaging lines.

Dilaudid

 Product transfer team is in place. Equipment has been transferred, and batch records have been finalized for experimental batches. Analytical method transfers are in process. Stability batches will be complete in April 2008.

MS Contin/Uniphyl

Produced a total of 16 batches during the 1st Q, primarily comprised of MSCR for Watson. Cycle
time targets were achieved approximately 72% of the time during the 1st Q and batch delivery
continued to meet 100%.

Process Improvement and Operational Efficiency

 Wilson: Cross training certificates were issued to 43 operators in Wilson allowing the Q1 increase in output to be achieved by swift transfer of fully trained staff to the required process areas.

Compliance

- Totowa: An alleged GMP compliance violation regarding the yielding of Uniphyl final blends was investigated over a 10-week period and confirmed to have occurred. The findings established that there was no adverse impact to product quality; however, the significance of the GMP violation resulted in the termination of two responsible manufacturing supervisory personnel and the subsequent resignation of the Sr. Director of Operations. An interim management structure is in place as replacements are being recruited.
- Totowa: pre-EU Inspection Audit was conducted at Totowa in late February by D. Begg and Associates with favorable results. Preparations continue for an IMB (Irish Medicines Board) inspection for OxyContin the week of 4/7.
- Wilson: DEA approved the Distribution registration awaiting final feedback regarding how Purdue should operate under this additional registration.

Facilities and Infrastructure

- Totowa
 - Garret Mountain/Totowa relocation project -On target for Q3 completion and the project has been sent out for bid to potential contractors.

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Wilson

- 1. Procurement of 60" tablet coater remains on target and within budget. Installation and qualification is scheduled in Q4 2008. Construction for facility modifications is underway. Equipment delivery has been delayed due to a manufacturing error of a nonround pan. Equipment delivery is now expected the last week of May.
- 2. RFID Gen 2/Merrill TIPS Hardware Upgrade installation and qualification for both packaging lines are complete.
- 3. Incoming RFID Gen2: This project is to install equipment in the warehouse for third party incoming RFID labeled bottles. The line will require new equipment, conveyor modifications and qualification. The overall completion date is scheduled for May 2008.

Logistics (Distribution)

- Total customer orders shipped to customers through March, 2008: 7,548 with 7,445 shipped complete (99%).
 - 1. Wilson (Narcotic) 1,134 total customer orders with 100% shipped complete.
 - 2. Louisville (Non-Narcotic) 6,407 total customer orders with 99% shipped complete.
 - 3. Total Purdue inventory as of March 2008 was \$36.2M. This is up from YE 2007 inventory of \$28.7M primarily due to a \$6M increase in OxyContin raw materials, work in process, and finished goods.

Logistics (3rd Party) - Contract Manufacturing & Packaging

- Anderson Packaging Activities are falling in line for 2nd quarter start up at this new premier supplier. Project has progressed to start Colace 100mg 10ct validation and Colace 100mg 2ct blisters in early April. Anderson will replace Catalent for these products. OTR blister stability work will also be executed at Anderson on April 2nd. Other products will be added to this supplier's portfolio for Purdue over the coming year.
- Aplicare A Supply Agreement amendment was negotiated and should be executed in April. An RFQ for the Betadine business was sent to Aplicare. Aplicare will formally present their quote at a meeting scheduled for April 8th. Cursory review of the quote was not favorable for Aplicare as compared to Thatcher's current pricing.
- Colace Capsules Mfg / Catalent FL Qualification and stability work is on-going for the transition to the new manufacturing process for Colace 50mg and 100mg capsules. Colace Capsules Pkg / Catalent PA- Final commercial packaging activity at Catalent, PA was received March 6th and released to market March 11th. No future Colace 100mg 10ct packaging is planned for this supplier. All work is being transferred to Anderson Packaging.
- Delpharm On October 19, 2007 Delpharm was officially notified that we will be terminating the agreement effective January 2009. A new work stream is in progress to have Time Cap Labs supply a slow release magnesium product to replace Delpharm. Delpharm has not been able to catch up with their deliveries, and we continue to experience delays. Product is being sent via air freight to expedite delivery and minimize schedule interruptions at Wellspring.
- OxyContin 20ct HUD's / Sharp February receipt of Oxy 20mg HUD's is under investigation due to crimp or hole in blister. Investigation has been on-going with root cause still to be identified by Sharp. All packaging runs are being postponed per Sharp until root cause is identified. This could pose a potential backorder situation in April for the 20mg continuing to work with Sharp to develop a solution to the problem and avoid a backorder.
- PL Developments A new business relationship is underway with PL Developments. A successful audit was performed in December and they were added to the approved supplier list in January. This enables Purdue to work directly with PL Developments for kit and display work only. Pricing from them has been very competitive for this work.
- <u>Thatcher Pharmaceutical</u> Supply agreement amended for 1 year (new expiry July 2009). Logistics is in the process of sending RFQ's to both Aplicare and Xttrium (both current approved suppliers) for alternate, competitive source evaluation as the Thatcher contract comes to term.

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- Time Cap Labs We a modification to the current Supply Agreement wherein Time Cap Labs sub-contracts packaging to PL Developments. In 2008 Purdue will be looking to separate the relationship and establish separate agreements with both entities, TCL for manufacturing and PL Developments for packaging. Additionally, a project team is on-going to support Time Caps Labs supplying a slow release magnesium product to replace Slow Mag currently supplied by Delpharm
- Wellspring Wellspring continues to be one of Purdue's premier suppliers. Colace and Peri-Colace new trade dress was launched March 24th week, 3 months earlier than originally planned due to unanticipated new distribution at Walgreens that depleted stocks sooner than expected.

DEA Manufacturing/Procurement Quota Status

- The DEA procurement quota process will be one of the keys to our success in 2008. With the
 rapidly increasing demand in OxyContin and the transition to OTR, the DEA quota allocations will
 be the governing factor in achieving our sales targets.
 - 1. Oxycodone:
 - The 2008 Procurement Quota for Oxycodone is 12,639 kgs (hcl) which includes an allocation to manufacture OTR Clinical batches in Totowa. This represents 45% of the API Purchasing Plan of 27,923 kgs based on the current DIP. Based on the significant increase in February sales, a request for an increase in allocation of 4,658 kgs was submitted in March, for which a response is expected in April.
 - Hydromorphone:
 The 2008 Initial Procurement Quota for Hydromorphone was established at 125 kgs (hcl) to support the manufacture of TR Scale-up/Clinical and Validation batches. Additional requests have been submitted to support the tech transfer for Dilaudid.
 - 3. Morphine:
 The 2008 Initial Commercial Quota for Morphine was issued at 2,292 kgs, all of which was purchased during the first two months. Watson's annual requirements from Purdue are approx. 3,100 kgs. Assuming sales continue at the current rate, an allocation request will be made mid-year to support the balance of requirements.

Supply Management Highlights:

- Supplier Right the First Time Performance in Q1 is 91% for deliveries through March to Purdue facilities vs. a goal of 90%.
- The new supply agreements with Noramco for both Purdue and Rhodes for Oxycodone, Morphine, Hydromorphone and Thebaine were executed in December, and in Q1 Purdue has purchased against the new pricing structure. Additionally, there were several key sourcing projects performed in Q1 2008. The highlights are below:
 - 1. Sourcing and qualifying Hydromorphone from Noramco for Dilaudid will yield a significant cost savings for this line in 2008.
 - 2. Sourcing Hydrocodone from Noramco for the development group to begin work on a Hydrocodone extended release tablet
 - 3. Sourced Low ABUK Oxycodone from Noramco (3 lots were shipped to Wilson in October). The team has developed a qualification plan which will ultimately have Noramco as a back up supplier to Rhodes by Q1 2009.
 - Negotiating with a two contract bulk manufacturer for an API (Micron and Regis Labs) to support the Discovery Group in Cranbury and the Shionogi project
 - Qualification of an alternate RFID tag supplier is completed. Avery's tag will be added to RFID product label packaging specification, and we continue to work with other label convertors to back up George Schmitt.
- Purchase Price Variance through February ran at \$357K due to procurement of Morphine from Mallinckrodt, the preferred lower cost supplier. Noramco could not supply in the time frame required to support production of MSContin.

QUALITY

Corporate Quality Compliance Services

- Compliance Status
 - 1. Each of the PPLP sites continues to have a favorable compliance status resulting in no significant observations from regulatory inspections.
 - 2. The CQA 2008 compliance program (internal and external vendor audits) is planned and several audits conducted. The audit program continues to be effective in identifying and correcting compliance gaps in the areas of GMP, GCP, GLP, and Information Systems. The GMP audits focused on the PAI readiness of Wilson and Cranbury, while the GCP audits concentrated on OTR and BUP clinical study reports. There were no critical observations for audits conducted in 1Q2008, and corrective action plans are in place for all audit observations.
- FDA 483 Commitments (summary)
 - Stamford All commitments from the July 2006 FDA Inspection have been completed.
 These were related to the time required to report serious unlisted Adverse Events from
 ex-US Associated Companies. The percentage of Adverse Events reported late has
 decreased indicating the effectiveness of actions taken to date. The October 2007 mock
 inspection corrective actions are 50% completed and efforts will continue to improve
 reporting effectiveness.
 - 2. Wilson All commitments from the January 2007 ANVISA (Brazilian) inspection and the verbal commitments made during the August 2007 FDA inspection are being addressed by Wilson personnel, tracked by CQA and will be independently verified by CQA.
 - OTR NDA Commitments made in the November 2007 submission (stability and process controls) are identified, tracked and independently verified by CQA.
- Commercial Product Complaints
 - The systems for managing complaints and conducting investigations are currently under control. There is no trend in product complaints evident at this time, and no actions are required. The actual number of complaints is well within statistical expectations based on historical results since 2004.
 - 2. For OTC products, the number of complaints received per million tablets sold is stable in the area of 1 complaint received per million tablets sold through February 2008.
 - For prescription products the ratio of complaints is comparable and low. The ratio of complaints to million tablets sold has dropped below 0.4 complaints per million of tablets sold for OxyContin, and approximately 0.6 complaints per million tablets sold for MSContin.

Wilson QA & QC

A mock PAI was conducted in Wilson in January 2008 to assess that logistics are in place for an inspection, and Wilson's compliance with the OTR submission, and readiness for OTR launch. The mock audit was conducted by Corporate Quality Compliance Services and included all OTR PAI associated personnel from Cranbury, Totowa, Garret, Wilson, and Stamford. The mock audit concluded there are no critical observations that could potentially impact the OTR submission approval and Wilson's ability to start OTR validation batches.

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 Wilson has implemented in-house water testing in QC, which will result in a savings of at least \$75,000 for contract testing by the end of the year.

Cranbury Research Quality Assurance (RQA)

Cranbury RQA has completed all preparations for their upcoming FDA Pre-Approval Inspection of the Analytical Sciences Operation. At FDA's request, Purdue filed for the Registration of the Cranbury Site as an Analytical Testing Laboratory at the end of January 2008. Purdue is still waiting for final confirmation of the Site's registration. Once the site has been assigned a Registration number, the PAI will be scheduled by the New Jersey FDA District.

Totowa QA & QC

- The Totowa Quality Organization has completed its preparations for the upcoming EU inspection of the site by the Irish Medicines Board. The purpose of the inspection is to qualify Totowa as a back-up OxyContin manufacturing facility for NAPP. The Inspection will be conducted on April 7 11, 2008. Preparations for this EU inspection have also ensured Totowa's readiness for an imminent general GMP inspection by the FDA. The site was last inspected by FDA in July 2006.
- The Uniphyl GMP Investigation was initiated on March 18, 2008, based on the Factual Summary provided by Corporate Legal. The GMP investigation is near completion and is evaluating the impact of this GMP violation on all products manufactured in Totowa. As the specific GMP violation occurred after the final granulation was completed, there was no impact to the uniformity or quality of the blended granulation. The final product impact assessments for OxyContin and MS Contin are near completion. The full results of this GMP investigation including root causes and corrective and preventive actions will be shared upon completion of the investigation. Company-wide training on this incident is also being planned to ensure that all sites understand the seriousness of this event.

Rhodes OA & OC

1. Rhodes QA has continued to keep the focus of the site on the importance of completing investigations and CAPAs in a timely manner. Improvement has been made with no late investigations in 2008, and the percent of late CAPAs dropping to 17% from 28% in 2007.

Supplier Quality Assurance (SQA)

 Dilaudid technology transfer has commenced at Wilson, utilizing the continuous improvement technology transfer template. Analytical method development for content uniformity, assay and dissolution are complete. Quality standard development for all raw materials are complete, except for the API.

Training

- Training curricula was implemented for the IT, PD&D, PKDM, CQA and Medical Research organizations, and metrics will be published accordingly.
- Training curricula is under development for the Corporate Security, Project Development, Regulatory, Health Policy and Risk Assessment organizations.

NON-CLINICAL DEVELOPMENT & TECHNICAL SERVICES

Analytical Sciences/Pharmaceutics

OxyContin Tamper Resistant

- 10-40mg NDA responses to all FDA questions to date have been provided and 10, 100 and 120 ct bottles are stable at 6 months accelerated and 12 months RT.
- 60-80mg 10 and 120 count stable at 6 months accelerated and 9 months RT.
- 60-80mg documentation for sNDA filing will complete April 30 for June filing.
- TR patent published.

Hydrocodone Q24h Tamper Resistant

Initial formulation development using TR platform underway.

Norspan

Additional supplies for BUP 3025 have been imported and released for clinical packaging.

Hydromorphone Tamper Resistant

- Studies in progress to evaluate impact of BHT with and without oxygen scavengers on rate of formation of N-oxide in HTR 12mg tablets. All data after 3 month stability storage too close to LOQ to discern differences.
- Internal formulation activities currently on-hold as resource is being used for hydrocodone Q24h development. External development partner not identified.

POA

All materials (API, excipient and packaging components) required for POA1001 are released.

Modi-Mundipharma Joint Projects

- Protocols and budgets received for initial clinical study using morphine. Anticipated dosing date by Modi is July 2008.
- Senokot Pediatric Chewable formulation development complete. Stability data acceptable for two batches after 6 months accelerated data. Optimization batches at commercial scale scheduled to be manufactured week of 24 March.

Wilson & Totowa Pharmaceutical Technology

- Oxycodone Tamper Resistant Tablets-10-40mg validation batches manufactured and validation reports are incorporating rolling data. All groups prepared for Pre Approval Inspection Wilson Pharm Tech hosted a technical team from Napp to support the Wilson to EU OTR transfer
 - 1. Tech Transfer of OTR to Totowa is on going with clinical supplies for the bio batches (10, 40 and 80 mg) available 7/31/08.
- Dilaudid:
- 1. First batch, replicating Abbott process, scheduled for week of 3/31 Method transfers underway, assay and content uniformity completed..
- Uniphyl:
- 1. Completed dissolution testing requirement requested by FDA on 01/08 from comments to the CMC section of the supplement to the Uniphyl 400/600mg ANDA.

- OTC Product Support:
 - 1. 3 pilot lots of Senokot Children's Chewable Tablets from Modi-Mundipharma are stable. Process optimization and scale-up started at the TCH facility in Modinagar, India 03/24/08.
 - 2. Process validation protocol for Colace Gel Capsules the 50 mg was approved.
 - 3. Technology transfer of Slow Magnesium Tablets from DelPharm, France to TimeCaps, NY is in progress with a target launch in 4Q08.

New Drug Safety Evaluation/Pharmacokinetics and Drug Metabolism - Norspan

- The final report of the TgAC mouse bioassay was issued including a post-study test article characterization report.
- Revised draft of Module 2.4 for the pending J-NDA submission was completed and circulated for technical review. Nonclinical sections of the J-NDA will meet the MKK submission date of Oct 2008

Hydromorphone Tamper Resistant

Bioanalytical reports for 3 BE studies (HTR1001, HTR1003 and HTR1004) were completed.

OCX (oxycodone/naltrexone)

Bioanalytical reports for 3 legacy studies (OCX1015, OCX1016 and OCX2002) were completed.

HYD (hydrocodone)

A nonclinical gap analysis for a US NDA was completed; protocols and pricing for 5 safety
pharmacology studies were obtained from CRL Montreal and MPI. The 2 previously suspended
carcinogenicity studies (mice and rats) were reactivated and costs/timing for completion under
negotiation with Covance.

OXN (oxycodone/naloxone) - US & Europe

- Preparations for the pk study in monkeys were completed.
- A revised CTD Section 2.6 that included new genotoxicity data for oxycodone was produced in support of projected Decentralized (DCP) and Multiple Region (MRP) submissions in Europe.
- Bioanalytical support was provided for OXN analyses performed at Taylor Technology in the US and HFL Ltd. in the UK.

V113741 (POA)

- The 3-month GLP rat and monkey study reports were finalized including bio-analytical method validation reports. An acute and 7-day repeat dosing study protocol was completed for initiation in O2 2008
- The Investigator Brochure for V113741 was updated with completed tox data.

Redacted

DHE Mundipharma Research Ltd. (UK)

 Extensive technical and expert support was provide including identification of nonclinical study requirements, selection of potential CROs and generation of protocol outlines.

PROJECT/ALLIANCE/OUTSOURCE MANAGEMENT

Alliance Management

Labopharm

- Labopharm has communicated to Purdue that they are not responsible for sharing costs relating to the Par defense litigation. Options to address are being pursued..
- Labopharm completed statistical analysis of their efficacy study and submitted it to FDA, via the appeal process with no firm response date established.
- Labopharm visited Purdue on March 6th to discuss their Mis-use Platform Technology and a
 potential new opportunity, a Tramadol/Acetaminophen combination product.



OTR Lessons Learned Special Project

To better understand OTR product development and registration intra-departmental interviews
with staff, at various levels, were conducted during the period of Nov 2007 thru Feb 2008. The final
report was issued to the R&D Operating Committee sponsors on March 24th.

Corixa/GSK

- Discussions with GSK have been centered around patents related to the molecule targeting the
 O772P antigen that were assigned to GSK upon the return of the license to Corixa back in July 2005;
- Purdue and GSK had agreed to transfer the patents back to Purdue and terminate the agreement (pending Board approval); on March 27th, GSK notified Purdue that they may not want to proceed.

Outsource Management

Contracting

Thirteen (13) contracts executed, twenty seven (27) contracts requested, three (3) clinical trial
agreements & grants were reviewed,(2) indemnification agreements completed and six (6)
indemnification agreements routed for completion.

Financial Performance

 Total Cost Savings = \$3,694,250. This is \$1,322,586 under SOP32.01 & \$2,371,663 in savings outside of SOP32.01

Vendor Relationship

- 2008 joint PRA/Purdue annual meeting was held in Atlanta January 2008 with the following process improvements identified:
 - 1. Grant development, grant negotiations and strategies to reduce grant costs
 - 2. Increased accuracy and timeliness of invoices
 - 3. Agreed on expectations for qualifying and negotiating contracts with 3rd party providers

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4. Developed grant payment schedules that allow cash flow but reduces payments for non-evaluable subjects and caps subject screen failures

Project Management

Dilaudid® Transition Team

- The following activities have been completed during the 1st quarter:
 - 1. Completion of second Asset Purchase Agreement
 - 2. Transfer of the Supply Agreement from Abbott/Hospira to Purdue/Hospira
 - 3. Establishment of Technical Operations meetings with Abbott in support of uninterrupted transition of supply and ongoing FDA filing requirements.
 - 4. Finalization of Purdue labeling to implement at the Abbott Whippany, NJ site and Hospira McPherson, KS site. Product to be labeled with Purdue name/NDCs beginning in July 2008. Transition from Abbott trade dress to Purdue trade dress will take effect with shipments to wholesalers September 29th 2008.
 - 5. Equipment qualification and Quality Control method transfer has completed in Wilson to support tablet development batches in April 2008.
- Abbott continues to run the day-to-day business operations regarding sales and distribution through the Distribution Period which will expire on June 30, 2008. At that point all activities will transfer to Purdue.

Product Assessment Group

- Comprehensive clinical, non-clinical, regulatory, marketing, operational and financial assessments were completed on the following products:
 - 1. Durect Eladur™ bupivacaine patch
 - 2. P&G Thermacare® OTC
 - 3. Light Science Litx™

Other

- Tracking of pharmacology and toxicology studies on project.pharma.com to be released May-08.
 Search capabilities across the system are being developed as part of the R&D Insight project and will be available May-08
- Completed department training on Medical Research's SOPs & WPDs

DISCOVERY RESEARCH

Redacted

 There are no significant Discovery Project updates for this report. An update will be provided 2Q08 after the Joint Steering Committee Meeting May 11-17 in Kyoto.

CLINICAL RESEARCH & DEVELOPMENT

PROJECT

Norspan US Submission - US

- Significant progress continues towards completing activities required for NDA submission in 2Q2009.
- Pre-NDA meeting request and briefing package to be sent April, 2008 with meeting anticipated July, 2008.
- Non-Clinical, CM&C, Risk Management and Supply Chain activities are progressing and off the critical path

Pivotal Study Update

- BUP3015 (Completed, positive study); e-published study report completed Tuesday, April 1st 2008
- BUP3024 (Ongoing, enrollment completed); all major study milestones are ahead of plan.
- 3. **BUP3025** (Ongoing, back-up pivotal study); actively enrolling, recent increase in enrollment rate (~40% randomized); recruitment vendor identified (Argonauta) and will be used to aid in enrollment

Norspan/BuTrans Ex-US

 Support ongoing and planned to continue for J-NDA filing in Japan, BUP 3015 final study report delivered for Canadian re-submission

HTR Project (Palladone)

- Results from HTR formulation stability experiments now anticipated 2Q08 (HNO production slower than expected under control conditions)
- Alternate formulation technologies being considered for further HTR development

Palladone NDA Phase IV Commitment

 HMP4009 Pediatric PK study enrollment at 50 (41 received oral HMP) of planned total of 100 subjects

HYD Project (Hydrocodone TR, Modified Release)

- Review of prior PPLP non-clinical and clinical development of hydrocodone products (HYIR, HYCR, HCD, HXA, HCX) over >10 years under review
- HYD Formulation and Clinical development strategies under discussion, focused on q24h product that conforms to our patent
- Target Product Profile submitted for review/approval, Product Development Plan being drafted

OxyContin-NF OTR

- 10-40mg NDA
 - 1. All CMC questions from FDA addressed
 - 2. 12-month stability data submitted
 - Validation batches completed
 - Blister packaging stability program underway

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- 4. Acceptable FDA audit of clinical site
- 5. Pre-approval inspection readiness completed at all sites
- 6. Background documentation for Advisory Committee meeting submitted
- 60,80mg sNDA
 - 1. CMC sections on schedule for submission to regulatory affairs late April
 - 2. Clinical sections finalized and submitted to regulatory affairs
- 10-80mg program
 - 1. Long-term epidemiology protocol and SPA submitted to FDA
 - 2. Internet monitoring program put in place
 - 3. Health economic model in development
 - 4. Activities supporting Tech transfer to Totowa underway

OXN

- Target product profile developed
- Completion of assessment of previous studies undertaken
- European/US combined meeting held
- US development strategy development undertaken

OxyContin

FDA request for revision of RiskMAP underway

POA

 First-in-man experiment (POA1001) to begin screening late April 2008 month rat and monkey toxicity studies completed with final CSRs in March 2008.

NON-PROJECT

Clinical Systems

• Implemented version 2 of the Medical Research Repository. The repository is the single system used to collect and manage all documents generated in the planning, execution and reporting stages of our clinical studies. This improvement will increase operating efficiency by enhancing the CRO's ability to search and access stored project data.

Document Management

 Developed a process for the management of all hard-copy study documents created by Medical Research personnel, a function previously handled by Regulatory Clinical Archives. The corresponding SOP is in the approval process and will be implemented 2Q08.

CRO Strategic Collaboration

- Successful 2nd annual meeting held with PRA on 30-31 January to review activities over the past
 year, evaluate lessons learned, and plan for future improvements all towards the goal of optimizing
 efficiencies in the outsourced model (including effective planning, implementation and execution of
 quality clinical development services).
- Multiple Purdue Pharma-specific PRA templates have been finalized and implemented: These
 include Data Management Plan Documents, Phase1 and Phase 2-3 Clinical Study Reports, Phase1
 Statistical Analysis Plans, and document for Pre-marketing Safety Assessment (PMSA)

RISK MANAGEMENT & HEALTH POLICY

Health Policy

- Consulted regularly with External Affairs Group on various topics, including litigation.
- Presently working with Chadbourne & Parke in preparation for depositions.
- Meetings & Presentations:
 - American Academy of Pain Medicine, BOD meeting, Co-Chair of Council of Past Presidents & Chair, External Affairs; American Board of Pain Medicine, BOD meeting & Chair, Examination Council, Kissimmee, FL on February, 11-18, 2008.
 - 2. PhRMA: "2008 FDA Dialogue session on abuse liability seminar in Bethesda, MD on February 20, 2008.
 - 3. Assisted with Focus Group for *Corporate Reputation Management* facilitated by Luntz, Maslansky Strategic Research Group in Alexandria, VA on February 20, 2008.
 - American Association of Dental Examiners Task Group with development of guidelines for State Dental Boards to evaluate cases where prescribing controlled substances are involved on February 22, 2008 and February 25, 2008.
 - Assisted with Focus Group facilitated by Synovate Research Group in Paramus, NJ on OTR Labeling February 28, 2008.
 - 6. Lawful Prescribing and Prevention of Diversion, invited presentation for the Maryland Society of Addiction Medicine in Baltimore, MD on March 1, 2008.
 - 7. Presented *Is It Pain?* to DMs in two workshop at the Manager's meeting on March 13, 2008. Wrote and recorded script for DVD voice-over for April District Meetings.
 - 8. Invited participant in think tank: *Towards a Definitive Evidence Base for Opioid Management of Chronic Non-Cancer Pain* sponsored by Milbank Memorial Fund and Mayday Foundation in Salt Lake City, UT on March 16-18, 2008.
 - 9. Participated on the Tufts Health Care Institute's program on Opioid Risk Management meeting in Boston, MA on March 27, 2008.
- Co-author, presenter of poster at AAPM meeting on routes of opioid analgesic administration preferred by nonmedical users of opioid analgesics.
- Co-author, manuscripts submitted under "Other Activities" in Risk Management section below.

Risk Management

Supported NDA Filing of OxyContin® (New Formulation)

- Implemented a study demonstrating economic costs associated with the abuse of opioid analyseics.
- Implemented Internet study to monitor "chatter" regarding abuse (including preferred routes of abuse) of OxyContin® (oxycodone HCl controlled-release) Tablets.
- Internet survey established baseline-level of OxyContin abuse pre launch of new formulation.
- Implemented community-based study of OxyContin abusers residing in Kentucky to determine preferred routes of nonmedical administration of OxyContin and opioid analysesics.
- Co-author of poster presented at the 2008 AAPM meeting listed under Health Policy above.

Supported Continued Marketing of OxyContin® (Original Formulation)

- Responded to FDA "Discipline Review Letter" by developing a RiskMAP for OxyContin[®] (old formulation) per FDA request – involved substantial change from previous RMP.
- Responded to FDA request for additional information on status of abuse-related risk management interventions.

Monitored Abuse and Diversion of PPLP's Marketed Opioid Analgesics

Added Dilaudid[®] to list of opioid analgesics monitored for Reports of Concern (ROCs).

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- 853 ROCs regarding abuse and diversion of PPLP marketed opioid analysesics reviewed and entered into the Risk Management DataMart for 1st Quarter 2008.
- 17 field inquiries conducted in response to signals of abuse or diversion of OxyContin as identified via review of ROCs, and RADARS® System data for 1st Quarter 2008..

Other Activities in Support of PPLP Risk Management Program

- Four risk management abstracts accepted for poster presentation at the 2008 annual meeting of College on Drug Dependence (CPDD).
- Submitted manuscript describing RxPATROL® and presenting recent data from the system submitted for peer-review to Journal of the American Pharmacists Association.
- Submitted manuscript describing new methodology for detecting "signals" of opioid analgesic abuse in RADARS® System surveillance data.
- Represented PPLP at WHO CIOMS Working Group on Signal Detection in Pharmacovigilance: Paris, March 2008.

Healthcare Education & Liaison Programs

Medical Education

- Certified, web-based programs (Pain, Constipation and/or Risk Management) funded by Purdue
 - 1. 40 active courses (Note: 2 renewals requiring no additional funding from Purdue)
 - 2. >180,000 Continuing Education Certificates earned in 2+ years
- Non-certified educational resource fulfillment to healthcare professionals, upon request
 - 1. 153 catalog orders YTD
 - 2. 3525 items ordered YTD
 - 3. Med Ed Resource Catalog
 - 4. Neuropathic Pain: Challenges & Considerations
 - 5. Complexities: Caring for People in Pain
 - 6. Pain: An Illustrated Resource Vol 1
 - 7. Pain: An Illustrated Resource Vol 3

Healthcare Grants and Giving Review Committee

Total grant requests reviewed: 1Q08 = 168
 Total approved (approval rate): 1Q08 = 59 (35%)
 Total amount funded (approval rate): 1Q08 = \$692,041 (17%)
 YTD=59 (35%)
 YTD=\$692,041 (17%)

Medical Liaisons

- Alliance Outreach
 - 1. Sent over 1200 personalized email messages to all state medical, pharmacy, and pain associations as well as state medical and pharmacy licensing boards announcing:
 - Partners Against Pain® Re-launch
 - OxyContin® Patent Update and New Strengths
 - 2. Collaborated with Washington State Pharmacy Association, Law Enforcement Liaison & Education department for publication of *Pharmacy Security: Prepare to Protect* by Ron D'Ulisse.
 - Reached 2000+ pharmacists and will be repurposed as Purdue Rep material for distribution.
 - Association also sent "Fax Alert" to members announcing new website link to RxPatrol®.
 - 3. Developed a new healthcare professional resource: *Medication Therapy Management: Focus on Pain Care* Tip Card for release through the Medical Education Resource Catalog.

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- Strategic Education
 - Coordinated a 3-part, 9-program web-based education series for Managed Care customers.
 - 450 healthcare professional encounters (average 150 per topic)
 - 62 Managed Care Organization encounters (average 20 per topic)
 - Of participants who completed post-presentation evaluations:
 - 97% reported the information was useful
 - o 75% indicated they would change their practice as a result of the information
 - 99% indicated the information was fair-balanced and free from commercial bias
 - Developed an electronic post-presentation participant evaluation tool enabling Medical Liaisons to gather and report metrics for non-accredited educational programs provided.
 - 3. Complete update/revision of 6 modules in *FACETS Volume* 2, for the Medical Education Resource Catalog.

Medical Inquiries

During 1Q08 Medical Services received 3,050 inquiries. This is a 10% increase from 4Q07 and a 2% decrease from 1Q07. Ninety percent of the 1Q08 inquiries were answered within one business day and 99% were answered within 10 business days.

Library & Information Services

Information Research

- Continued to investigate the commercial importance of Novartis' European patents in anticipation
 of pending patent office opposition deadlines. To date, the library has undertaken major search
 projects on 56 Novartis patents and our research has identified several that may be susceptible to
 challenge after further legal investigation. This work supports an important contribution to our
 commercial strategy
- Added online access to key resources:
 - 1. New England Journal of Medicine
 - Books 24X7 to provide efficient, electronic access to IT handbooks at all sites and reduce print costs
 - 3. General Engineering and Engineering Management collection of e-books to support facility maintenance and renovation at manufacturing and research sites.
- Developed alert profiles to create a literature monitoring program for Dilaudid. Established underlying database structure to integrate Dilaudid literature into PharmaSearch.
- Completed the review of 1800 OxyContin records in PharmaSearch and created links to full text for 902 publications and reports.

REGULATORY AFFAIRS, DRUG SAFETY SURVELIENCE

Regulatory Affairs

V113741 (POA) Development Activities

A protocol amendment for the first in human study POA1001 was submitted to FDA on March 7, 2008. This fulfills our agreement with FDA, documented in our letter of May 23, 2007, to submit this amendment including all of the changes to the protocol discussed with the Division during our teleconferences on May 16 and 22, 2007. With this submission, POA1001 may now proceed to enroll subjects.

Licensing & Business Development

 Due Diligence site visits were conducted for Litx's oncology combination (talaporfin plus light drug/device) product (January 22-23, 2008 in Bellevue, WA) and Durect's bupivacaine patch (March 19-20, 2008 in Cupertino, CA). Regulatory Due Diligence reports have been completed.

Labeling, Advertising & Communication

- RAPL completed the transition of all the Abbott Dilaudid acquisition labeling components to full Purdue content by the expected due date of April 1, 2008.
- A Medication Guide for OTR was developed expeditiously based on FDA request.

Reformulated OxyContin

- Review is continuing with mainly CMC questions and Risk Management questions being asked.
- Advisory Committee Meeting needed to include physical properties in the label. Planning is underway.

OxyContin

- On January 7, 2008 we submitted a Written Waiver Request regarding six additional legal settlement agreements, which FDA responded that they agree with our proposal.
- On January 15, 2008 we submitted a Written Waiver Request for the 2006 Annual Report for King County Medical Examiner's Office and on February 20, 2008 a Waiver Request for the American Association of Poison Control Center's 2006 Annual Report, both waivers were granted as requested. [In addition to OxyContin, these two waivers were a multi-product submission including Palladone, MS Contin, and Dilaudid]

Uniphyl

On February 6, 2008 Purdue received a non approval letter for a "Prior Approval Supplement (S-016) which was to provide for alternate manufacturing sites and associated changes. (Bioequivalence has not been established). Purdue filed a notification of Intent to file an amendment on 2/20/2008.

Chemistry, Manufacturing and Controls

FDA Submissions

- OTR
 - 1. NDA Amendment was submitted 15 February to provide 12 month stability data.
 - 2. FDA has made several requests for information concerning the OTR NDA and the CMC group has responded with multiple submissions over the past 3 months.

LA Submissions

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- Norspan/Restiva/Soloro New registrations for Brazil, Mexico and Venezuela: 20 March, Purdue Legal Department authorized release of BTDS dossier to Grunenthal Venezuela. All CMC, clinical and non-clinical volumes sent via Accellion 24 March.
- OxyContin New registrations for Costa Rica and Panama: Response to deficiencies from 2005 registrations in progress. Awaiting revised stability reports from Wilson.
- OxyIR New registrations (multiple countries): Dossiers and registration documents (signed, paper) sent to all Tecnofarma associated licensees in Latin America 4Q07 Anticipate 2Q08 submissions in AR, BO, CL, EC, PE, and VE.. Dinafarma's (Mexico) request for hermeticity data resolved. Results sent to Sanfer/Dinafarma 15 February.
- Multiple requests for documentation to support re-registrations in various countries for various products were received and answered.
- Certificate of Pharmaceutical Product (CPP) OxyContin 10, 20 and 40 mg tablets. A total of 6 new CPPs (2 countries) were obtained in 2008.
 - 1. Panama: 3 CPPs issued 21 February. Apostille received 07 March.
 - 2. Venezuela: 3 CPPs issued February 27. Apostille received 05 March.
 - 3. Ecuador: 3 CPPs issued 14 December 2007. Apostille received 11 January

EU Submissions

Norspan second wave MRP has been closed at Day 60 by the Reference Member State Denmark. European regulatory affairs are collating all the comments received from the Concerned Member States to revise the wording of the indication and the other text changes required. A Type II variation will be filed by the end of March. This submission will include all 20 member states that are involved in the first and second round procedures which is a 90 day process. Feedback is anticipated by the end of May and hopefully resolution in June of this year.

Compliance/Quality Actions

- Change Controls 96
- Deviations 1
- Participated in Stamford Quality Council

Regulatory Document Management

FDA Submissions

During 1Q08 there were **79** Submissions to the FDA including but not limited to 22 IND Safety Reports for buprenorphine, and for OTR 12 eCTD submissions RE: Amendments to pending application submissions and/or Response to Request for Information.

Dossier Compilation

In this quarter there have been **21** clinical study report publications to support the buprenorphine resubmission including but not limited to BUP3015,BP99-0203R, BP98-1201R, BP96-0604R, BP96-0501R, BP96-0101R, BP96-0102R, BP96-0901R, BP96-0304R, BP96-0702R, BP96-0803R, BP96-1102R, BP97-0112R, BP97-0501R, BUP3002, and for hydromorphone HMP 1014

Regulatory Systems

The installation of G2 (the new regulatory documentum system is complete and the entire buprenorphine set of documents have been migrated from GRASP to the new system. It is anticipated that the OxyContin document archive will be similarly migrated by the end of May.

Paper Archive

The entire GCP paper archive (previously housed on p3 has been inventoried and archived off site at Iron Mountain

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Drug Safety and Pharmacovigilance

- Achieved 97% YTD compliance in USA-origin expedited submissions to FDA for 5,707 total case report volume processed as of December 31, 2007
- Processed 6,147 litigation cases (measured independently from 2007 volume count above)
- DSP processing of 21 Litigation Settlements closed or in progress an additional 5 settlements expected by June 2008
- DSP process improvement: Collaboration with IT to develop solution managing DSP emails.
- IPAES AE System Upgrade project: Installed Argus Safety v4.2 development environment. Milestones are on-time.
- In 2007 3,426 initial and follow-up telephone calls were handled by Product Monitoring. Of the 3,426 calls, 2,138 concerned adverse events (or reports of concern) and 1,288 were product complaints.
- During 2007 99% of the 536 product complaints received by Product Monitoring were closed on time in accordance with SOP. 319 of the 536 product complaints met the criteria (i.e., Lot # or sample was available, or was a critical PC) for further investigation by the manufacturing site.

HUMAN RESOURCES

Staffing Overview

• A total of 45 employees have been hired as of March 31, 2008. Turnover YTD is 1.3% compared to 1.1% as of March 31, 2007.

Growth

• Dr. Catherine Munera, Director, Biostatistics and Statistical programming has been chosen as Purdue's first Rising Star Award recipient and will be honored at the annual Women of the Year event hosted by the Healthcare Businesswomen's Association, in May. This HBA award recognizes up-and-coming professionals in various sectors of the healthcare industry, including pharmaceutical, biotechnology, advertising, public relations, medical education and market research, among other fields. Rising Stars are nominated by HBA's corporate members; the recipients represent various career disciplines and the award is given to those who have demonstrated noteworthy achievements and proven attention to furthering their careers.

Productivity

A FACIS (Fraud and Abuse Control Information System) check has been completed on all employees
to ensure that no employee has been excluded, debarred, suspended or deemed otherwise ineligible
to participate in federal healthcare programs. The results of this company-wide review confirms that
all current employees are "sanction free."

Compensation

 The 3rd bonus award under the Milestone Achievement Program, for the attainment of the return of OxyContin® to exclusivity in the 12-hour oxycodone market, has been issued to employees.

Facilities

The renovation of 158,605 RSF at 1600 Summer Street was completed on time and approximately \$2 million under the estimated construction budget. Driven by the April 1 deadline for turning over the 7th and 8th floors of One Stamford Forum to UBS. 327 individuals were relocated from One Stamford Forum to Summer Street and 79 individuals were relocated within the One Stamford Forum Facility. The Broad street population, totaling 49, will be relocated to Summer Street on April 11 & 12, completing the current reorganization. In all, 455 individuals will have been relocated during non-business hours over the course of 12 separate moves.

Employee Health & Safety

- In compliance with The National Fire Protection Association a successful audit has been completed
 on flammable liquids at the Rhodes facility by Carson Associates.
- OSHA has enacted a specific standard covering the handling of combustible dust in compliance with The US Chemical Safety Board. Purdue received a notification from OSHA for all sites and is conducting a review to assure compliance. A one-day training program has been held on the topic of Dust Explosion Hazards in Totowa, provided by consultant, Chilworth. The training includes combustibility testing, safeguards to minimize any potential hazards and proper safe handling procedures. Over 20 colleagues from Operations, Engineering and EHS throughout the company were in attendance. A second session will be held in Wilson later this year.

UNREDACTED - CONTAINS OUTSIDE PROFESSIONALS' FYES ONLY INFORMATION 19-23649-snl - CONTAINS OUTSIDE PROFESSIONALS' FYES ONLY INFORMATION TREAT SUBJECT TO BE CAREATION And Exhibits Part 1 Pg 63 of 68

Full-Time Turnover Projection

March YTD 2008

Marketing 3 Sales Support 1 Field Ops, Sup & Admin 2 Total S&P 3 % of X-FTE's	304 32 16 20	304 34 14	1 0	0.3%		EE's		Resigned		% Rate	Turnover %
Field Sales 3 Marketing 3 Sales Support 1 Field Ops, Sup & Admin 2 Total S&P 3 % of X-FTE's	32 16 20	34		0.3%				_			
Marketing 3 Sales Support 1 Field Ops, Sup & Admin 2 Total S&P 3 % of X-FTE's	32 16 20	34			0	0.0%	3	1.0%	4	1.3%	10.6%
Sales Support 1 Field Ops, Sup & Admin 2 Total S&P 3 % of X-FTE's	16 20			0.0%	0	0.0%	0	0.0%	0	0.0%	20.0%
Field Ops, Sup & Admin Total S&P % of X-FTE's	20		1	6.3%	0	0.0%	0	0.0%	1	6.3%	0.0%
Total S&P 3		21	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5.6%
% of X-FTE's		373	2	0.5%	0	0.0%	3	0.8%	5	1.3%	10.7%
			40.0%		0.0%		60.0%				
G&A											
	31	31	0	0.0%	0	0.0%	0	0.0%	0	0.0%	6.3%
	6	5	0	0.0%	0	0.0%	1	16.7%	1	16.7%	0.0%
	5	6	0	0.0%	0	0.0%	0	0.0%	0	0.0%	33.3%
	0	0	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0.0%
	4	4	0	0.0%	0	0.0%	0	0.0%	0	0.0%	33.3%
	11	11	0	0.0%	0	0.0%	0	0.0%	0	0.0%	25.0%
	11	12	0	0.0%	0	0.0%	0	0.0%	0	0.0%	11.1%
	56	58	0	0.0%	0	0.0%	0	0.0%	0	0.0%	18.5%
	48	48	0	0.0%	0	0.0%	1	2.1%	1	2.1%	6.6%
	20	20	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4.8%
	79	80	0	0.0%	0	0.0%	1	1.3%	1	1.3%	3.0%
	9	9	0	0.0%	0	0.0%	0	0.0%	0	0.0%	28.6%
	19	19	0	0.0%	0	0.0%	0	0.0%	0	0.0%	25.0%
	14	14	0	0.0%	0	0.0%	0	0.0%	0	0.0%	9.1%
	813	317	0	0.0%	0	0.0%	3	1.0%	3	1.0%	10.6%
% of X-FTE's	10		0.0%	0.070	0.0%	0.0.70	100.0%	1.0 /0	2.52	1.00	10.0
IRD/US			0.070		0.070		100.070				
	39	42	0	0.0%	0	0.0%	0	0.0%	0	0.0%	7.7%
<i>-</i>	30	33	0	0.0%	0	0.0%	0	0.0%	0	0.0%	7.4%
_	30	29	1	3.3%	0	0.0%	0	0.0%	1	3.3%	4.0%
	47	48	0	0.0%	0	0.0%	0	0.0%	0	0.0%	13.0%
	34	35	0	0.0%	0	0.0%	0	0.0%	0	0.0%	17.2%
	18	19	0	0.0%	0	0.0%	0	0.0%	0	0.0%	5.6%
5 0	17	17	0	0.0%	0	0.0%	1	5.9%	1	5.9%	6.7%
	215	223		0.5%	0	0.0%	1	0.5%	2	0.9%	9.2%
% of X-FTE's	27,000	223	50.0%	0.0.70	0.0%	0.0.70	50.0%	70.00	1 12 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	0.0	2,47,0
MFG/OPERATIONS			270.070		0.070		50.070				
	43	42	2	4.7%	0	0.0%	0	0.0%	2	4.7%	51.6%
	43 39	38	3	7.7%	0	0.0%	0	0.0%	3	7.7%	39.4%
	53	54	0	0.0%	0	0.0%	0	0.0%	0	0.0%	13.7%
	55 92	105	0	0.0%	0	0.0%		1.1%		1.1%	22.9%
	92 147	152	0	0.0%	0	0.0%	1	0.7%	1	0.7%	5.6%
	147 374	391	5	1.3%	0	0.0%	1 2	0.7%	1 7	1.9%	23.7%
% of X-FTE's	//	JJ1	71.4%	1.0/0	0.0%	U ₁ U 70	28.6%	U.S 70		1.770	23.170
	3	3	0	0.0%	0.0%	0.0%	28.0%	0.0%	0	0.0%	0.0%
% of X-FTE's			0.0%	0.0 /0	0.0%	0.0 70	0.0%	U•U 70	V:	U•U 70	0.070
	277	1,307	8	0.6%	0.0%	0.0%	9	0.7%	17	1.3%	14.4%

LICENSING & BUSINESS DEVELOPMENT

Abbott: Dilaudid® (hydromorphone)

Completed part II U.S. March 31, 2008; Purdue now owns Dilaudid in U.S.

Redacted

Business Development Committee

- Launched new "Business Development Committee" which replaces the "NPLC." This new structure will facilitate:
 - renewed focus on internal new product development
 - 2. IP and technology out-licensing
 - 3. In-licensing of products which meet the criteria in the comprehensive analgesic plan

CORPORATE COMPLIANCE

Corporate Integrity Agreement

The Compliance Officer received a letter dated April 4th from OIG seeking clarification of three points and a copy of a document in connection with Purdue's November 28, 2007 Implementation Report. These are minor non-substantive clarifications with respect to the intent and operation of three SOPs produced to OIG with the Implementation Report. We submitted our reply to OIG on April 10th.

State Filings

All required state law filings concerning sales and marketing expenditures on prescribers and
others have been timely filed, including pursuant to the new West Virginia "emergency rule," on
March 1st (nothing significant reported), and the timely payment of \$1000 to the state of Maine with
respect to the MaineCare program, on April 1st.

No "Major Issues"

• Hotline and Other Inquiries - We investigated a total of 83 Hotline and other matters during the first quarter of 2008. None of these matters were of significant concern or indicative of compliance failures sufficient to warrant reporting to the Board or to applicable regulatory or other authorities. The Board is aware of the previously reported investigation into recent Uniphyl batch production anomalies. Another matter involved a hotline caller's reported concern about production anomalies with respect to developmental batches of OTR, as to which investigation confirmed management awareness and satisfactory addressing of the concern.

FINANCE DEPARTMENT

Financial Performance

- Q1 2008 Gross Sales before rebates were \$471 million or \$58 million under budget. The \$58 million under budget was primarily due to \$62 million lower trade inventory of OxyContin than budget (timing) offset by \$9 million higher OxyContin demand. We believe this shortfall is temporary and that sales will meet or exceed the revised budget!
- Purdue ended Q1 with \$575.2 million of unrestricted cash plus \$81.9 million of restricted cash. This
 cash earns between 2% and 3% and is invested in US Treasury debt/US Agency debt and high grade
 commercial paper. The maturities of these investments are short, the credit quality is high and
 maturities are coordinated with our anticipated financial obligations.
- We expect to issue audited 2007 financials by mid-April.
- For reference see: E. Mahony email 4/4/2008 March Flash Report

Banking

Certain Purdue executives and Board members met with JP Morgan Chase and Goldman Sachs to explore the viability of borrowing \$1 to \$2 billion to fund potential future acquisitions, make distributions or a mix of the two. Both banks were cautiously optimistic that such a borrowing would be possible. However, in view of current turmoil in the financial markets, the banks were not definite. Our next step is to update our 5 year plan, which will become the basis for a deeper analysis by the banks and also part of a road show package.

Insurance Renewals

Since 2001 Purdue has not purchased Product Liability Insurance. In anticipation of the new tamper
resistant form of OxyContin being on the market late this year, we believe that Product Liability
Insurance may once again become available. In coordination with Legal and Regulatory we will
begin to explore this with insurers in June or July.

Authorized Generic

We have engaged Deloitte Financial Advisory Services to conduct an audit of Watson's records to
assure compliance with the October 2005 Distribution and Supply agreement and the related
February 2007 Termination agreement. Deloitte is currently reviewing Watson records and an
update will be provided as information becomes available.

AG -"be prepared"

 On February 13th 2008 we signed a new OxyContin AG Distribution and Supply Agreement with Watson. Under this agreement Watson is ready to launch AT PURDUE'S OPTION.



Generic Inventory

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Generic oxycodone ER in the trade available to consumers in 2008 is estimated at 1.6 million bottles.
 As of 3/31/08, we estimated generic inventory that remains to be consumed, is 0.8 million bottles.
 We project the majority of the remaining generic inventory will be consumed by the end of 2008.

Product Liability Insurance Proceeds

- Purdue is currently seeking payments under the 2nd excess layer policies of the Oxy Tower (127M to 227M layer) in which three insurers participate: Zurich (25%); Gerling (25%); and XL/Winterthur (50%). To date, we have collected the following:
 - 1. Zurich and Gerling: 100% of their respective shares or \$2.3 million.
 - 2. XL/Winterthur: 0% (Our legal team is exchanging letters with XL/Winterthur but, at the moment; do not expect to collect their respective share of this layer for some time).
- Cumulatively, we have now collected approximately \$320 million from Zurich, Gerling, AIG and Gulf.

Ardsley Property

 The Board approved lease proposal was sent to Columbia on March 24th. We plan to meet with Columbia face-to-face on April 11th, to review the proposal. Columbia remains interested, but slow.

Real Estate Taxes / Personal Property Taxes

The City of Stamford is in the process of re-evaluating real estate values used for assessing real estate taxes paid by property owners. This comes at a time when central business district properties appear to have materially increased in value and residential properties may have decreased in value. If the City's initial values are accepted, the tax on One Stamford Forum would increase:

From: \$1.8 million To: \$3.2 million

The City invited property owners to informally meet with the City's appraisers to dispute their valuation. Jon Lowne, Ed Mahony and outside counsel met with the City twice and as a result the expected taxes could change as follows:

From: \$1.8 million To: \$2.9 million

Of this increase 60% would be absorbed by UBS, but the remaining 40% (or \$440,000) would be absorbed by One Stamford Realty. We believe this increase is not correct and we will appeal.

Tax

The IRS audit of BR Holdings Associates L.P. will begin on April 28 for three days. The agent has
asked for information, which is currently being gathered.

PROCUREMENT

- Corporate Procurement, IT and HR negotiated a consulting services agreement for the conversion of Purdue's PeopleSoft system to SAP. Initial bids were at \$1,000 per day. As a result of competitive bidding and off-shoring, this cost was cut to \$500 per day, saving about \$1.0 MM.
- Sales and Corporate Procurement negotiated and implemented the use of recruiting services of a
 contract sales organization to recruit the recently approved 100 new sales reps. This contract will
 allow Purdue to recruit the new reps in one third the time at a savings of \$1 million dollars over our
 traditional recruiting method with no sacrifice in quality.
- Corporate Procurement and IT renegotiated our MCI/Verizon telecom agreement for a two year term. This agreement reduced the annual commitment from \$600k to \$200K, included a \$110K credit and will result in savings for the two years totaling \$910K.

 Corporate Procurement and Creative Services & Marketing negotiated a 31% reduction in cost of the PDR supplement for our latest OxyContin PI. This is significant because Thomson PDR historically has not negotiated their rates.

INFORMATION TECHNOLOGY DEPARTMENT

Continuous Improvement

- IT's Continuous Improvement team, working with Manufacturing, R&D, and Quality colleagues developed a tech transfer SOP template (called the Blue Book) formalizing roles, responsibilities, duration, etc. in each step of a tech transfer. This process will first be used to transfer Dilaudid to Wilson and OTR to Totowa. The process is expected to improve compliance, reduce cycle time and reduce staff resources, For example:
 - 1. Experimental batch records for Dilaudid just completed were approved within 2 days vs. 15 days for similar work on OTR in 2007.
 - Review and approval of development (work plan) documents was streamlined from 8 reviews to 4 reviews.

Sales & Commercial Systems

- Pharmacy stocking data is now provided to the Field Force via their Phoenix system. This is proving to be a big help in the launch of OxyContin's new strengths.
- As part of Risk Management, a pilot Retail Order Monitoring System was created to detect
 pharmacies with unusual OxyContin purchasing behavior. This new system reports purchasing
 patterns across multiple wholesalers that might not be visible to a single wholesaler.
- A new Sales Force call note tracking system was established in 1Q to further ensure field force oversight and compliance with the Corporate Integrity Agreement.

R&D

- Regulatory Affair's new electronic Common Technical Document (eCTD) system is in place and will be available to the R&D disciplines in April.
- The European Regulatory submission system will separate from the US system in 2Q once all European product data has been moved.
- Consolidation of Regulatory, Clinical Research, Toxicology and Project Management documents into a central repository, and providing cross-discipline searches based on a custom R&D Dictionary of Terms, project R&D Insight, is on track for delivery in 2Q.
- The Adverse Event System upgrade is on schedule for completion in 4Q and rollout in 1Q2009.

Manufacturing & Quality

- A new automatic stability study initiation system went live in Wilson and Totowa in Q1. Going
 forward, the system will notify appropriate personnel to ensure that stability studies are initiated and
 completed as required by the FDA. This system should reduce compliance risk associated with
 missed studies.
- Wilson Batch Disposition Enhancements were completed in 1Q to ensure we meet commitments
 made to the FDA. The new functionality enables QA to review online batch disposition check lists,
 verify with dual electronic signature, and print out Certificate of Compliance and Inspection Reports.
- Representatives from IT, State Government, and Legal Affairs reported to the California Board of Pharmacy on progress toward compliance with California's Drug Pedigree initiative, which goes into effect 1Q2009. The Board was impressed with Purdue's RFID and product serialization efforts and recognized Purdue as leaders the industry in this area.

RHODES

Financial

YTD financial results are in line with budget.

Dronabinol Launch

Based on recent communications with FDA, we expect to launch dronabinol with Par in Q2, 2008.
 This is in line with our budget. The Par/Rhodes dronabinol joint Marketing Committee will meet this week to agree on final launch plans.

Narcotic Raw Material (NRM) Registration

Rhodes is working with counsel and others to progress the application. We are hopeful that the
application will achieve final approval by 2009.

Rhodes R&D

Oxycodone Ultra Low ABUK program: In support of Purdue's OTR submission, Rhodes R&D agreed with the FDA to determine if FDA's new proposed limit on ABUK's (essentially <1 part per million vs. the current level of <10 parts per million) can be achieved. Work is planned to start in the first half of 2008 when additional staff is brought on board. Rhodes advised the FDA that this process could take 18 months to complete, but hopes to complete the work sooner.</p>

Hydrocodone:

- 1. Process development is nearing completion
- 2. Method transfer to QC began in Q1 2008
- 3. Analytical method development and validation is underway
- 4. Validation of the first 3 steps of the process is planned for mid-2008
- 5. Validation of the final process step will be in Q4, 2007.
- NALS: This project is being progressed by four (4) process chemists. These chemists are assigned to
 complete synthetic route scouting and selection. Current efforts are focused on naloxone to support
 Targin in the EU. Validation of the process is currently planned for the first half of 2009.
- Hydromorphone: Development work is scheduled to start in Q3 2008.

Rhodes Pharmaceuticals (New Gen Co)

- During Q4 2007, agreement was reached to create Rhodes Pharmaceuticals, a generic-based finished dosage pharmaceutical company. Recruiting for the CEO is in process. One very good candidate, Mark Hartman, is identified. The search continues in order to find an equally qualified candidate who will relocate to Coventry.
- Bob Kupper is progressing the effort to generate ANDA's for the new company as quickly as possible. For example, technical transfer of the first product (Immediate Release Oxycodone) from Canada to Wilson is planned for ~mid-2008. Shortly there after, combination products (oxy/APAP) will follow.

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